

What is claimed is:

1. A lateral flow assay for detecting the quantity of analyte residing in a test solution, the assay comprising:

(a) a plurality of probes, the probes being configured for generating a detectable signal, wherein the probes are capable of combining with analyte to form a probe conjugate analyte complex;

(b) a membrane, the membrane being configured for mobilizing a test solution containing both probes and probe conjugate analyte complexes, the membrane comprising:

(i) a detection zone, the detection zone having deposited thereon an immobilized first capture reagent, wherein the immobilized first capture reagent is configured for bonding with probe-conjugate analyte complexes to form sandwich complexes that generate signals;

(ii) a calibration zone, the calibration zone comprising at least first and second control lines, wherein the first and second control lines each have applied thereon a predetermined amount of a second capture reagent, the second capture reagent being configured to immobilize probes upon the first and second control lines to form control probe complexes capable of generating a control signal.

2. The lateral flow assay of claim 1, further comprising:

(c) a comparison means for comparing the intensity of signals generated by control probe complexes positioned upon said first and

second control lines with the intensity of signals generated by sandwich
complexes positioned upon the detection zone.

3. The lateral flow assay of claim 2, further wherein a calibration curve is generated using signal intensity data generated by control probe complexes positioned upon the control lines.

4. The lateral flow assay of claim 1 in which the probe comprises a microparticle that is capable of generating a visual signal.

5. The lateral flow assay of claim 4 in which the microparticle is capable of generating a color intensity.

6. The lateral flow assay of claim 1 in which the probe is capable of generating a fluorescent signal.

7. The lateral flow assay of claim 1 in which the probe comprises a microparticle.

8. The lateral flow assay of claim 7 in which the microparticle exhibits a color intensity.

9. The lateral flow assay of claim 2 in which a detection device is provided for detecting signals generated by control probe complexes positioned upon respective control lines with the intensity of signals generated by sandwich complexes positioned upon the detection zone.

10. The lateral flow assay of claim 2 wherein the probe comprises a microparticle, further wherein the comparison means comprises a device adapted for comparing intensity of light signals generated from

the first and second control lines with the intensity of signals generated
by sandwich complexes positioned upon the detection zone.

11. The lateral flow assay of claim 10, further wherein a
calibration curve is generated using signal intensity data from the first
and second control lines.

12. The lateral flow assay of claim 11 in which an automated
system of generating the curve and performing the comparison is
provided.

13. A method of detecting the quantity of an analyte present in a
test solution, the method comprising:

(a) providing a membrane with a test solution containing analyte;

(b) providing a plurality of probes and probe conjugates upon the
membrane;

(c) binding the probe conjugates with the analyte to form probe
analyte conjugates;

(d) wherein the membrane comprises a first end and a second
end, the membrane having a first capture reagent immobilized upon a
detection zone, the membrane being configured for mobilizing a test
solution containing probe-analyte conjugates from the first end to the
second end of the membrane;

(e) capturing within a detection zone probe-analyte conjugates,
thereby forming immobilized signal generating sandwich complexes
within the detection zone;

(f) providing a calibration zone upon the membrane, the calibration zone comprising at least first and second control lines having predetermined amounts of a second capture reagent immobilized upon said control lines;

20 (g) capturing, with the second capture reagent, probes upon the first and second control lines by forming control probe complexes upon said control lines;

(h) generating a first set of control signals from the control probe complexes;

25 (i) generating a second set of measured signals from the sandwich complexes in the detection zone; and

(j) comparing the control signals to the measured signals to determine the quantity of analyte present in the test solution.

14. The method of claim 14, wherein prior to step (j), the method further comprises the step of generating a signal intensity curve, further wherein step (j) comprises comparing control signals to the signal intensity curve to provide a determination of the quantity of analyte present in a test solution.

15. The method of claim 14 in which the probe comprises a microparticle that is capable of generating a signal.

16. The method of claim 15 in which the microparticle is capable of generating a color intensity.

17. The method of claim 16 in which the microparticle is a latex bead.

19. The method of claim 13 in which a third control line is employed.

21. The method of claim 19 in which the probes comprise latex beads.

22. The method of claim 21 in which latex beads further include coloring agents for providing a visually detectable signal.